

**Notice of Allowability**

Application No.

09/729,043

Examiner

Celine X Qian

Applicant(s)

BRADSHAW ET AL.

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1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 1/9/04.
2. ☒ The allowed claim(s) is/are 21-25, 29-31, 38 and 39.
3. ☒ The drawings filed on 04 December 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

The after final amendment filed on 1/9/04 has been entered.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 2/18/04, Applicant's representative requested an extension of time for one month and authorized the Director to charge Deposit Account no. 13-4500 the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claims 14-17 and 20 are cancelled.

Claim 29. A method of producing a transgenic mouse having integrated into its genome a defined segment of DNA, comprising:

- a. obtaining a yeast-bacteria shuttle vector comprising a yeast replication origin, a yeast selection marker gene, a bacterial replication origin, a bacterial selection marker gene, at least one unique cloning site, and sequences homologous to sequences flanking the defined segment of DNA, wherein said bacterial replication origin is selected from the group consisting of P1 replicon and F factor origin of replication;
- b. linearizing the vector within the homologous sequences to form recombinogenic ends;

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- c. introducing the linearized vector into a yeast cell containing DNA comprising the defined segment of DNA, wherein the linearized vector and defined segment of DNA homologously recombine to form a recombinant product;
- d. selecting for the recombinant product;
- e. transferring the recombinant product to bacteria for amplification;
- f. isolating the defined segment of DNA from the recombinant product;
- g. integrating the defined segment of DNA into a specific site in the genome of embryonic stem cells by homologous recombination;
- h. isolating the embryonic stem cells having integrated into their genome the defined segment of DNA;
- i. injecting the embryonic stem cells of step (h) into a blastocyst;
- j. transferring the blastocyst to a pseudopregnant mouse and allowing the blastocyst to develop into a [transgenic]chimeric mouse;
- k. identifying the [transgenic] chimeric mouse that has integrated into its genome the defined segment of DNA;
- l. breeding the [transgenic] chimeric mouse to identify offspring comprising [germ-line transmission of] the defined segment of DNA in its germ line; and
- m. breeding the germ-line transmitting offspring to produce a transgenic mouse having integrated into its genome the defined segment of DNA.

Claim 38. A method for establishing a transgenic, non-human mammalian line comprising: producing a transgenic, non-human mammal according to the [The] method of

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claim 21 and further [comprising] breeding the transgenic, non-human mammal to establish a transgenic, non-human mammalian line.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER